PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For PHS internal use only:

License Number:

License Application Number:

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Licensee:

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

Additional Remarks:

Public Benefit(s):

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**".

PHS PATENT LICENSE AGREEMENT – *EXCLUSIVE*

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.2 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.3 "**First Commercial Sale**" means the initial transfer by or on behalf of **Licensee** or its sublicensees of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.4 "**Government**" means the Government of the United States of America.

2.5 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.6 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.6(a):

(i) continuations-in-part of 2.6(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.6(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.6(a): all counterpart foreign and U.S. patent applications and patents to 2.6(a) and 2.6(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.6(b) or 2.6(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.6(a).

2.7 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.8 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.9 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.10 "**Net Sales**" means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of **Licensee** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee**, or sublicensees, and on its payroll, or for the cost of collections.

2.11 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.12 "**Research License**" means a nontransferable, nonexclusive license to make and to use **Licensed Products** or **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by **PHS** and which shall not be unreasonably withheld, **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**.

4.2 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to **PHS** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 **Licensee** agrees to forward to **PHS** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, **PHS** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 (a) **PHS** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, **Licensee** agrees to provide **PHS** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use; and

(b) In the event that the **Licensed Patent Rights** are Subject Inventions made under a Cooperative Research and Development Agreement (**CRADA**), **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice **Licensed Patent Rights** or have **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the **First Commercial Sale**, **Licensee** agrees to provide **PHS** reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.

5.2 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

5.3 **Licensee** acknowledges that **PHS** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with **PHS** when acquiring these rights is necessary in order to make a **CRADA** project feasible. **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) In addition to the reserved license of Paragraph 5.1, **PHS** reserves the right to grant **Research Licenses** directly or to require **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, **PHS** shall consult with **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) In exceptional circumstances, and in the event that **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by **Licensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or

(iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(b) The determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(2).

6. ROYALTIES AND REIMBURSEMENT

6.1 **Licensee** agrees to pay **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 **Licensee** agrees to pay **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 **Licensee** agrees to pay **PHS** earned royalties as set forth in Appendix C.

6.4 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.

6.5 **Licensee** agrees to pay **PHS** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses, or

(c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of **Licensed Products** by **Licensee** to sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and incurred by **PHS** prior to the effective date of this **Agreement**, **Licensee** shall pay **PHS**, as an additional royalty, within sixty (60) days of **PHS'** submission of a statement and request for payment to **Licensee**, an amount equivalent to these patent expenses previously incurred by **PHS**.

6.10 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and incurred by **PHS** on or after the effective date of this **Agreement**, **PHS**, at its sole option, may require **Licensee**:

(a) to pay **PHS** on an annual basis, within sixty (60) days of **PHS'** submission of a statement and request for payment, a royalty amount equivalent to these patent expenses incurred during the previous calendar year(s);

(b) to pay these expenses directly to the law firm employed by **PHS** to handle these functions. However, in this event, **PHS** and not **Licensee** shall be the client of the law firm; or

(c) in limited circumstances, **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide **PHS** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 **PHS** agrees, upon written request, to provide **Licensee** with summaries of patent prosecution invoices for which **PHS** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10.

6.12 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to **PHS** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, **PHS** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish copies of relevant patent-related documents to **Licensee**.

7.2 Upon **PHS'** written request, **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to **PHS**. In this event, **Licensee** shall, subject to the prior approval of **PHS**, select registered patent attorneys or patent agents to provide these services on behalf of **Licensee** and **PHS**. **PHS** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. **Licensee** and its attorneys or agents shall consult with **PHS** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide **PHS** sufficient opportunity to comment on any document that **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, **PHS** may provide **Licensee** with written notice that **PHS** wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**. If **PHS** elects to reassume these responsibilities, **Licensee** agrees to cooperate fully with **PHS**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and to provide **PHS** with complete copies of any and all documents or other materials that **PHS** deems necessary to undertake such responsibilities. **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of **PHS'** choice.

7.4 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.1 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of **PHS**, by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due.

8.2 **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the **Licensed Products** or **Licensed Processes** are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalties owed to the **Government** under this **Agreement**, and whether the royalties owed have been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, **Licensee** has provided **PHS** with the **Commercial Development Plan** in Appendix E, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for these differences. In the annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee's** performance under this **Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written approval by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 CFR §404.3(d). **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **PHS** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

9.3 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 **Licensee** shall submit to **PHS**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 **Licensee** agrees to forward semi-annually to **PHS** a copy of these reports received by **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to **PHS** by **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to **PHS** at its address for **Agreement** Notices indicated on the Signature Page.

9.7 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments.

9.8 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 CFR §5.65(d).

10. PERFORMANCE

10.1 **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D. The efforts of a sublicensee shall be considered the efforts of **Licensee**.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.3 **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available on a compassionate use basis to patients, either through the patient's physician(s) or the medical center treating the patient.

10.4 **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code, **Licensee** may:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take such actions; and

(d) If **Licensee** desires to initiate a suit for patent infringement, **Licensee** shall notify **PHS** in writing. If **PHS** does not notify **Licensee** of its intent to pursue legal action within ninety (90) days, **Licensee** shall be free to initiate suit. **PHS** shall have a continuing right to intervene in the suit. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code or other statutes, **Licensee** may:

(a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and

(d) If **PHS** does not notify **Licensee** of its intent to respond to the legal action within a reasonable time, **Licensee** shall be free to do so. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If **Licensee** elects not to defend against the declaratory judgment action, **PHS**, at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by **Licensee**. The value of any recovery made by **Licensee** through court judgment or settlement shall be treated as **Net Sales** and subject to earned royalties.

11.5 **PHS** shall cooperate fully with **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. **PHS** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 **PHS** offers no warranties other than those specified in Article 1.

12.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon **Licensee**'s receipt of written notice.

13.4 **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving **PHS** sixty (60) days written notice to that effect.

13.5 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS'** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by the license **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, **PHS** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS'** concerns as to the items referenced in 13.5(a)-13.5(g). If **Licensee** fails to alleviate **PHS'** concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to **PHS'** satisfaction, **PHS** may terminate this **Agreement**.

13.7 When the public health and safety so require, and after written notice to **Licensee** providing **Licensee** a sixty (60) day opportunity to respond, **PHS** shall have the right to require **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. **PHS** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with **Licensee**.

13.8 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

13.9 Within thirty (30) days of receipt of written notice of **PHS**' unilateral decision to modify or terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.10 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **PHS** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of the destruction thereof.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned by **Licensee** except:

(a) with the prior written consent of **PHS**, this consent shall not to be withheld unreasonably; or

(b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**.

14.8 **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**, and **Licensee** shall pay **PHS**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within thirty (30) days of the assignment.

14.9 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.10 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

14.11 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve **PHS** patent rights in those countries.

14.12 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of **NIH**, **FDA**, **PHS**, or **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of **PHS**.

14.13 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

14.14 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.15 Paragraphs 4.3, 8.1, 9.5-9.7, 12.1-12.5, 13.9, 13.10, and 14.13 of this **Agreement** shall survive termination of this **Agreement**.

14.16 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For **PHS**:

_____ _____

Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by:

_____ _____

Signature of Authorized Official Date

_____

Printed Name

_____

Title

I. Official and Mailing Address for **Agreement** notices:

_____

_____

_____

_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____

Name

_____

Title

Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.

II.

III.

IV.

V.

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

(a)

II. **Licensed Territory:**

(a)

APPENDIX C – ROYALTIES

Royalties:

I. **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of _____ dollars ($X) within thirty (30) days from the effective date of this **Agreement.**

II. **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty in the amount of _____ dollars ($X) as follows:

The first minimum annual royalty is due within thirty (30) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. **Licensee** agrees to pay **PHS** earned royalties of _____ percent (X%) on **Net Sales** by or on behalf of **Licensee** and its sublicensees.

IV. **Licensee** agrees to pay **PHS Benchmark** royalties within thirty (30) days of achieving each **Benchmark**:

(a)

(b)

(c)

(d)

(e)

V. **Licensee** agrees to pay **PHS** additional sublicensing royalties of ____ percent (X%) on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense.

APPENDIX D – BENCHMARKS AND PERFORMANCE

Licensee agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

I.

II.

III.

IV.

V.

VI.

VII.

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank

ABA# 021030004
TREAS NYC
BNF=/AC-75080099
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

(301) 496-7735 extension 214

Please make checks payable to: *NIH/Patent Licensing*

*The OTT Reference Number **MUST** appear on checks, reports and correspondence*